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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/644,874

Applicant(s)

NARANG, UPVAN

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/24/04; 12/21/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The receipt is acknowledged of applicants' IDS filed 03/24/2004 and IDS field 12/21/2004.

Specification

1. Specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-60 of U.S. Patent No. 6,579,469, claims 1-34 of U.S. Patent No. 6,585,967, claims 1-49 of U.S. Patent No. 6,767,552 claims 1-49 of U.S. Patent No. 6,602,496, and claims 1-36 of U.S. Patent No. 6,942,875. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and each of the issued claims are directed to composition comprising polymerizable monomer and phenolic compounds applied to the skin. The phenolic agent are recited in claim 1 of '469 patent, claim 11 of '967 patent, claim 15 of '552 patent, claim 15 of '496 patent and claim 14 of '875 patent.

4. Claims 1-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over any of the following patents in view of WO 97/32613 ('613) or US 5,800,803 ('803), the patents are:

Claims 1-19 of U.S. Patent No. 5,981,621, particularly claim 9,
Claims 1-50 of U.S. Patent No. 6,143,352, particularly claim 13,
Claims 1-30 of U.S. Patent No. 6,306,243, particularly claim 16,
Claims 1-7 of U.S. Patent No. 6,310,166, particularly claim 2,
Claims 1-37 of U.S. Patent No. 6,352,704, particularly claim 2,
Claims 1-47 of U.S. Patent No. 6,455,064, particularly claim 11,
Claims 1-102 of U.S. Patent No. 6,512,023, particularly claim 2,
Claims 1-76 of U.S. Patent No. 6,605,667, particularly claim 2,
Claims 1-41 of U.S. Patent No. 6,746,667, particularly claim 2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and each of the issued claims are directed to adhesive composition comprising polymerizable monomer including cyanoacrylate. However, the issued patents do not claim antimicrobial agents in the composition.

WO 613 teaches wound dressing comprising acrylate polymer and triclosan that provides continuous control of growth of a broad range of microorganisms and promotes better wound healing (abstract; page 2, 2nd and 3rd full paragraphs; page 3, 4th full paragraph; page 5, 1st and 4th full paragraphs; page 6, 3rd and 4th full paragraphs; page 7, 1st and 3rd paragraphs).

US '803 teaches antibacterial agents that are showed increased uptake to the dental tissues when combined with acrylate polymers, such antibacterial agents include chlorinated and brominated phenol compounds (abstract; col.2, lines 15-17, 44-55).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate for tissue application as claimed by any of the issued patents, and further add triclosan to the composition as disclosed by WO '613, motivated by the teaching of WO 613 that triclosan provides continuous control of growth of a broad range of microorganisms and promotes better wound healing; or add any of the chlorinated and brominated phenol compounds as disclosed by US '803 motivated by the teaching of US '803 that chlorophenol and bromophenol compounds show increased uptake to the dental tissues when combined with polymers, with reasonable expectation of having composition comprising cyanoacrylate and antimicrobial agent selected from chlorinated or

brominated phenol compounds that has effective antimicrobial effect at the site of application.

5. Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of copending Application No. 10/355294 and claims 1-41 of copending Application No. 10/429,050. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: the instant claims and each of the copending claims are directed to composition comprising polymerizable monomer and phenolic antimicrobial agent applied to the skin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-66 of copending Application No. 09/964,415 in view of WO '613 or US '803. The instant claims the conflicted claims are directed to adhesive composition comprising

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polymerizable monomer including cyanoacrylate. However, conflicted claims do not recite antimicrobial agents in the composition.

The teachings of WO '613 and US '803 are discussed above.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate for tissue application as disclosed by conflicted claims, and further add triclosan to the composition as disclosed by WO '613, motivated by the teaching of WO 613 that triclosan provides continuous control of growth of a broad range of microorganisms and promotes better wound healing; or add any of the chlorinated and brominated phenol compounds as disclosed by US '803 motivated by the teaching of US '803 that chlorophenol and bromophenol compounds show increased uptake to the dental tissues when combined with polymers, with reasonable expectation of having composition comprising cyanoacrylate and antimicrobial agent selected from chlorinated or brominated phenol compounds that has effective antimicrobial effect at the site of application.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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8. Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for composition comprising octyl-cyanoacrylate monomer and triclosan, does not reasonably provide enablement for all the polymerizable monomers and all the antimicrobial agents, and all the phenolic compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is composition comprising polymerizable monomer and antimicrobial agent, and method of its production.

The breadth of the claims: The claims are very broad. The complex nature of the claims is exacerbated by the breadth of the claims. The claims encompasses

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myriad of monomer and myriad of antimicrobial agents including all the phenolic compounds.

The state of the prior art: The state of the art does not recognize all composition comprising any polymerizable polymers and any antimicrobial compounds. The state of the art recognizes acrylate monomers and antimicrobial compounds.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The guidance given by the specification on polymerizable polymers other than cyanoacrylate and antimicrobial agent other than triclosan is absent. Guidance for composition comprising octyl cyanoacrylate and triclosan is provided. It is not obvious from the disclosure of octyl-cyanoacrylate and triclosan if the other polymerizable monomer and all other antimicrobial agents will work. *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re*

Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of significant guidance from the specification or prior art with regard to composition comprising polymerizable monomer and antimicrobial agent, other than octyl cyanoacrylate and triclosan makes practicing the claimed invention unpredictable in the terms of using other polymerizable monomer and other antimicrobial agents in all the different possible combinations.

The presence or absence of working examples: The specification discloses only octyl-cyanoacrylate and triclosan in example 1. No working examples to show using any other monomer with any of the other claimed antimicrobial agents. Therefore, the specification has only enabled octyl-cyanoacrylate and triclosan.

The quantity of experimentation necessary: Therefor, the practitioner would turn to trial and error experimentation to practice the instant invention directed to composition comprising polymerizable monomer and antimicrobial agent, and method of its making without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 7, 12, 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. The expression "substantially" does not set forth the metes and bounds of the claim. Recourse to the specification does not define the expression "substantially".

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-4, 7-14, 16-19, 21-24, 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/23150 ('150).

WO '150 disclosed composition comprising cyanoacrylate and chlorophenol that form film when applied to the tissues (abstract; page 5, lines 20-25; page 7, lines 25; page 14, lines 29-30). The period of stability of the composition is inherent.

13. Claims 1-5, 7-12, 16-22, 28-29 rejected under 35 U.S.C. 102(b) as being anticipated by US 6,281,265 ('265).

US '265 disclosed composition comprising curable polymerizable monomer and antimicrobial triclosan that polymerize in situ (abstract; col.6, lines 34, 54-60; col.7, lines 17-30, 60-63; col.9, lines 6-7). The period of stability of the composition is inherent.

14. Claims 1, 7-16, 21-29 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,310,166 ('166).

US '166 disclosed sterile adhesive composition comprising cyanoacrylate monomer and phenol compound (abstract; col.11, line 58). The period of stability of the composition is inherent. The composition is made by placing the mixture of polymerizable cyanoacrylate monomer and phenol in container, close and sealing the container, and sterilizing the mixture and the container using heat or gamma irradiation (col.5, lines 6-48).

15. Claims 1, 7-16, 21-29 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,352,704 (704).

US '704 disclosed sterile adhesive composition comprising cyanoacrylate monomer and phenol compound (abstract; col.9, line 43). The period of stability of the composition is inherent. The composition is made by placing the mixture of polymerizable cyanoacrylate monomer and phenol in container, close and sealing the container, and sterilizing the mixture and the container using heat or gamma irradiation (col.4, lines 14-60).

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16. Claims 1-4, 7-12, 16-19, 21-22, 28-29 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,455,033 ('033).

US '033 disclosed composition comprising curable polymerizable monomer and antimicrobial o-benzoyl-p-chlorophenol compound (abstract; col.5, lines 37-39; col.6, lines 15-20). The period of stability of the composition is inherent.

17. Claims 1-4, 7-19, 21-26, 28, 29 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,579,469 ('469).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '496 disclosed composition comprising cyanoacrylate and chlorophenol compound (abstract; col.3, lines 63-66; col.21, lines 3-6; table II). The composition is made by placing a mixture of the ingredients in container and phenol, close and sealing the container, and sterilizing the mixture and the container (abstract). The composition is stable for 24 hours (col. 5, lines 10-25).

18. Claims 1, 2, 7-17, 21-29 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,585,967 ('967).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '967 disclosed composition comprising cyanoacrylate and phenol compound (abstract; col.6, lines 26, 63;). The composition is made by placing a mixture of the ingredients in container and phenol, close and sealing the container, and sterilizing the mixture and the container using heat or gamma irradiation (abstract; col.9, lines 25-50). The period of stability of the composition is inherent.

19. Claims 1, 2, 7-17, 21-29 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,602,496 ('496)

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '496 disclosed composition comprising cyanoacrylate and phenol compound (abstract; col.12, lines 45, 57; col.13, line 50). The composition is made by placing a

mixture of the ingredients in container and phenol, close and sealing the container, and sterilizing the mixture and the container using heat or gamma irradiation (col.9, lines 41-53). The period of stability of the composition is inherent.

20. Claims 1, 2, 7-14, 16, 17, 21-24, 28, 29 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,767,552 ('552).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '552 disclosed composition comprising curable polymerizable monomer and phenol compound (abstract; col.13, lines 17-20; col.15, line 56). The period of stability of the composition is inherent.

21. Claims 1, 2, 7-14, 16, 17, 21-24, 28 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,942,875 ('875).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

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the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '875 disclosed composition comprising curable polymerizable monomer and phenol compound (abstract; col.13, lines 17-20; col.14, line 10). The period of stability of the composition is inherent.

22. Claims 1, 2, 7-17, 21-29 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2004/0223946 ('946)

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '946 disclosed composition comprising cyanoacrylate and phenol compound (abstract; paragraphs 0022, 0023; 0052, 0053; claims 8, 17). The composition is made by placing a mixture of the ingredients in container and phenol, close and sealing the container, and sterilizing the mixture and the container using heat or gamma irradiation (col.9, lines 41-53). The composition is stable for 1 year (paragraph 0043).

23. Claims 1, 2, 7-14, 16, 17, 21-24, 28, 29 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2004/0151688 ('688).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '688 disclosed composition comprising curable polymerizable monomer and phenol compound (abstract; paragraphs 0017, 0039, 0044claims 6, 17). The period of stability of the composition is inherent.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US WO 150, US '265, US '166, US 704, US '033, US 469, US '967, US '496, US '552, US '875, US '946, US '688 each in view of US '803.

The teachings of the reference are discussed above. WO 150, US '265, US '166, US 704, US '033, US 469, US '967, US '496, US '552, US '875, US '946, US '688 do not teach bromophenol compounds as claimed in claim 6, which are taught by US '803.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate and antimicrobial agent as disclosed by any of WO '150, US '265, US '166 or US '704, US '033, US '469, US '967, US '496, US '552, US '875, US '946, US '688 and replace the antimicrobial agent by brominated phenol compounds disclosed by US '803, motivated by the teachings of US '803 that bromophenol compounds show increased uptake to the dental tissues when combined with polymers, with reasonable expectation of having composition comprising cyanoacrylate and brominated phenol compounds that has effective antimicrobial effect at the site of application.

26. Claims 15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 150, US '265, US '033, US '552, US '875, US '688 each in view of US '166.

The teachings of the reference are discussed above. WO 150, US '265, US '033, US '552, US '875, US '688 do not teach the composition is sterile, which is taught by US '166.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate and antimicrobial agent as disclosed by any of WO '150, US '265, US '033, US '552, US '875, US '688 and further sterilize the composition as disclosed by US '166, motivated by the teaching of US '166 that sterilization shows low levels of tissue toxicity, with reasonable expectation of having safe sterile composition comprising cyanoacrylate and antimicrobial that exhibits no tissue toxicity.

27. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '469 in view of US '166.

The teachings of the reference are discussed above. US '469 does not teach the method of sterilizing the composition, which is taught by US '166.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate and antimicrobial agent as disclosed by any of WO '150, US '265, and further sterilize the composition by heat or gamma irradiation as disclosed by US '166, motivated by the teaching of US '166 that sterilization shows low levels of tissue toxicity, with reasonable expectation of having safe sterile composition comprising cyanoacrylate and antimicrobial that exhibits no tissue toxicity.

28. Claims 4 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '150, US '469, each in view of WO 613.

The teachings of the references are discussed above. WO '150 and US '469 do not specifically teach triclosan as antimicrobial agent, which is taught by WO '613.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate for tissue application as disclosed by WO '150, and replace the chlorophenol by triclosan as disclosed by WO '613, motivated by the teaching of WO 613 that triclosan provides continuous control of growth of a broad range of microorganisms and promotes better

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wound healing, with reasonable expectation of having composition comprising cyanoacrylate and triclosan that provides continuous control of growth of a broad range of microorganisms.

29. Claims 2-5, 17-20 rejected under 35 U.S.C. 103(a) as being unpatentable over US '166, US '704, US '033, US '967, US '496, US '552, US '875, US '946, US '688 each in view of WO '613.

The teachings of the references are discussed above. US '166, US '704, US '033, US '967, US '496, US '552, US '875, US '946, US '688 do not specifically teach chlorinated phenol compounds as antimicrobial agent, which is taught by WO '613.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate for tissue application as disclosed by any of US '166, US '704, US '033, US '967, US '496, US '552, US '875, US '946, US '688 and replace the chlorophenol by triclosan as disclosed by WO '613, motivated by the teaching of WO 613 that triclosan provides continuous control of growth of a broad range of microorganisms and promotes better wound healing, with reasonable expectation of having composition comprising cyanoacrylate and triclosan that provides continuous control of growth of a broad range of microorganisms.

30. Claims 13, 14, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '265, US 033, each in view of US 6,666,870 ('870).

The teachings of US '265 and US '033 are discussed above, however, US '265, US 033 do not teach cyanoacrylate monomer in particular as claimed in claims 13, 14, 23, and 24.

US '870 teaches medical adhesives including cyanoacrylate as the advantageous medical adhesive because it is nontoxic, biocompatible, long lasting and moisture tolerant (col.4, lines 44-59).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate for tissue application as disclosed by any of US 265 and US '033, and replace the monomer by cyanoacrylate as disclosed by US '870, motivated by the teaching of US '870 that cyanoacrylate is nontoxic, biocompatible, long lasting and moisture tolerant, with reasonable expectation of having composition comprising nontoxic biocompatible cyanoacrylate suitable for medical uses.

31. Claims 1-14, 16-24 and 28-29 are rejected under 35 U.S.C. 103(a) as being obvious over US 5,981,621 ('621), US 6,143,352 ('352), US 6,306,243 ('243), US 6,455,064 ('064), US 6,512,023 ('023), US 6,605,667 ('667), US 6,746,667 ('667), US 2003/0082116 ('116) each in view of WO '613 and US '803.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

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the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

The references all teach polymer composition comprising cyanoacrylate for wound closure, as discussed before under double patenting rejection.

The references do not teach chlorophenol and bromophenol as antimicrobial agents in the composition, which are disclosed by WO '613 and US '803.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate for tissue application as disclosed by any of the references, and further add triclosan to the composition as disclosed by WO '613, motivated by the teaching of WO 613 that triclosan provides continuous control of growth of a broad range of microorganisms and promotes better wound healing; or add any of the chlorinated and brominated phenol compounds as disclosed by US '803 motivated by the teaching of US '803 that bromophenol compounds show increased uptake to the dental tissues when combined

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with polymers, with reasonable expectation of having composition comprising cyanoacrylate and antimicrobial agent selected from chlorinated or brominated phenol compounds that has effective antimicrobial effect at the site of application.

32. Claims 15, 25-27 are rejected under 35 U.S.C. 103(a) as being obvious over any of US '621, US '352, US '243, US '064, US '023, US '667, US '667, US '116 in view of WO 613 or US '803 and further in view of US '166.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

The teachings of US '621, US '352, US '243, US '064, US '023, US '667, US '667, US '116 in view of WO 613 or US '803 are discussed above. The combination of the references does not teach the method of making the composition and its sterilization, which is taught by US '166.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cyanoacrylate and antimicrobial agent as disclosed by any of US '621, US '352, US '243, US '064, US '023, US '667, US '667, US '116 in view of WO 613 or US '803, and further sterilize the composition by heat or gamma irradiation as disclosed by US '166, motivated by the teaching of US '166 that sterilization shows low levels of tissue toxicity, with reasonable expectation of having safe sterile composition comprising cyanoacrylate and antimicrobial that exhibits no tissue toxicity.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Isis Ghali
Examiner
Art Unit 1615

IG



ISIS GHALI
PATENT EXAMINER